K102910

510(k) SUMMARY
PDG Product Design Group DEC 23 2010
Luna Manual Wheelchair

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

PDG Product Design Group, Inc.
Unit 102-366 E. Kent Avenue South
Vancouver, British Columbia
Canada V5X 4N6
Contact Person:

Edward A. Kroll
President, Spectre Solutions, Inc and
Representative Consultant for PDG Product Design Group
5905 Fawn Lane
Cleveland, Ohio 44141

Date Prepared: September 4, 2010

Name of Device and Name/Address of Sponsor

PDG Product Design Group, Inc.
Unit 102-366 E. Kent Avenue South
Vancouver, British Columbia
Canada V5X 4N6
Contact Person:

Common or Usual Name

Wheelchair

Classification Name

Wheelchair, Mechanical

Predicate Device

Invacare Model 9000 Bariatric Wheelchair (K002317)

Intended Use

To provide mobility to persons limited to a sitting position

Technological Characteristics and Substantial Equivalence

A. Device Description

The PDG Model Luna wheelchair is manually operated, self propelled mechanical wheelchair. Its intended function and use is to provide mobility to persons that may be limited to a seated position. It may also be used as attendant propelled transport device in a health care environment such as a hospital, nursing home or extended care facility.

B. Substantial Equivalence

The Luna is substantially equivalent to **Invacare Corporation Model 9000 Bariatric Wheelchair** (Invacare 9000). The Invacare 9000 was granted marketing clearance by FDA on August 25, 2000 under 510(k) Accession Number K002317.

Performance Data

The Luna manual wheelchair is designed to meet the applicable requirements of ISO 7176 – Standard for Manual, Mechanical Wheelchairs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PDG Product Design Group, Inc.
% Spectre Solutions, Inc.
Mr. Edward A. Kroll
President
5905 Fawn Lane
Cleveland, Ohio 44141

DEC 2 3 2010

Re: K102910
Trade/Device Name: Luna Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 4, 2010
Received: October 1, 2010

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102910

DEC 23 2010

Device Name: Luna Mechanical Wheelchair

Indications for Use:

To provide mobility to persons limited to a seated position.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102910